K102025

5.0 510(k) Summary

AUG 11 2010

In accordance with 21 CFR 807.87(h) and (21 CFR 807.92) the 510(k) Summary for the Combat Ready Clamp is provided below.

Device Common Name: Vascular Clamp

Device Proprietary Name: Combat Ready Clamp

Submitter:
Combat Medical Systems, LLC
6441-D Yadkin Rd
Fayettville, NC 28303

Contact:
Calley Herzog
Consultant
Biologics Consulting Group, Inc.
Phone: 720-883-3633
Email: cherzog@bcg-usa.com

Classification Regulation: 21 CFR 870.4450, Class II, 510(k)

Panel: Cardiovascular

Product Code: DXC

Predicates: K002767 Compressar Femoral Access Compression Device

Indication for Use:
The Combat Ready Clamp is indicated for use in the battlefield to control difficult bleeds in the inguinal area.

Device Description:
The Combat Ready Clamp is designed to be used by Military medical personnel in the battlefield. The device is designed to control bleeding in the inguinal area where standard tourniquets cannot be used. The device can be used instead of manual pressure, allowing the medic to attend to other injuries or soldiers. The Combat Ready Clamp is used to control a difficult bleed for up to 4 hours until the injured soldier can be transferred to evacuation personnel for further treatment.

Non-clinical Performance Testing:

The Combat Ready Clamp was testing via bench testing to show that it could provide pressures equivalent to the predicate device.

The Combat Ready Clamp was also tested with a cadaver model to show that it was capable of stopping simulated vessel blood pressure.

Substantial Equivalence:

Based on technological characteristics the Combat Ready Clamp has been shown to be substantially equivalent to the predicate device, the Compressar Femoral Access Compression Device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center – WO66-0609
Silver Spring, MD 20993-0002

AUG 11 2010

Combat Medical Systems, LLC
c/o Biologics Consulting Group, Inc.
Ms. Calley Herzog
13417 Quivas St.
Westminster, CO 80234

Re: K102025
Trade/Device Name: Combat Ready Clamp
Regulation Number: 21 CFR 870.4450
Regulation Name: Vascular clamp
Regulatory Class: Class II (two)
Product Code: DXC
Dated: July 16, 2010
Received: July 19, 2010

Dear Ms. Herzog:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K102025

4.0 Indications for Use Statement

510(k) Number (if known): _K102025_

AUG 11 2010

Device Name: Combat Ready Clamp

Indications For Use:

The Combat Ready Clamp is indicated for use in the battlefield to control difficult bleeds in the inguinal area.

Prescription Use _X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use_____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K102025